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APPENDIX A

Text of Proposed Regulation

The following new section is added to 21 CFR:

21 CFR §101.____. Nutrient content claims for carbohydrate content of foods.

(a) *General requirements.* A claim about the level of carbohydrate in a food may only be made on the label or in the labeling of foods if:

- (1) The claim uses one of the terms defined in this section in accordance with the definition for that term;
- (2) The claim is made in accordance with the general requirements for nutrient content claims in §101.13;
- (3) The food for which the claim is made is labeled in accordance with §101.9, §101.10, or §101.36, as applicable; and
- (4) For dietary supplements, claims for carbohydrate may not be made on products that meet the criteria in §101.60(b)(1) or (b)(2) for “calorie free” or “low calorie” claims.

(b) *Carbohydrate content claims for foods that contain low or reduced levels of carbohydrates.*

(1) The terms “carbohydrate free,” “free of carbohydrate,” “no carbohydrate,” “zero carbohydrate,” “without carbohydrate,” “negligible source of carbohydrate,” or “dietarily insignificant source of carbohydrate” may be used on the label or in labeling of foods, provided that:

(i) The food contains less than 0.5 gram (g) of carbohydrate per reference amount customarily consumed and per labeled serving (excluding dietary fiber and the non-caloric proportion of sugar alcohols, as described in paragraph (c) of this section) or, in the case of a meal product or main dish product, less than 0.5 g of carbohydrate per labeled serving (excluding dietary fiber and the non-caloric proportion of sugar alcohols, as described in paragraph (c) of this section); and

(ii) The food contains less than 0.5 g per labeled serving of the total of dietary fiber and the non-caloric proportion of sugar alcohols (as described in paragraph (c) of this section), unless it is labeled to disclose that the claim is based on carbohydrates that provide calories, excluding dietary fiber and the non-caloric proportion of sugar alcohols (for example, “Free

of carbohydrates that provide calories (which excludes fiber and some sugar alcohols)"). This disclosure must appear immediately adjacent to or as part of the claim; and

(iii) The food contains no added ingredient that is a carbohydrate or is generally understood by consumers to contain carbohydrate (excluding dietary fiber and sugar alcohols) unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states "adds a trivial amount of carbohydrate," "adds a negligible amount of carbohydrate," or "adds a dietarily insignificant amount of carbohydrate;" and

(iv) As required in §101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower carbohydrate content, it is labeled to disclose that carbohydrate is not usually present in the food (e.g., "vegetable oil, a carbohydrate free food").

(2) The terms "low carbohydrate," "low in carbohydrate," "contains a small amount of carbohydrate," "low source of carbohydrate," or "little carbohydrate" may be used on the label or in labeling of foods, except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:

(i) –

(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 6 g or less of carbohydrate (excluding dietary fiber and the non-caloric proportion of sugar alcohols, as described in paragraph (c) of this section) per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 6 g or less of carbohydrate (excluding dietary fiber and the non-caloric proportion of sugar alcohols, as described in paragraph (c) of this section) per reference amount customarily consumed and per 50 g of food (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in §101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50-g criterion refers to the "as prepared" form); and

(ii) The food contains less than 0.5 g per serving of the total of dietary fiber and the non-caloric proportion of sugar alcohols (as described in paragraph (c) of this section), unless it is labeled to disclose that the claim is based on carbohydrates that provide calories, excluding dietary fiber and the non-caloric proportion of sugar alcohols (for example, "Low in carbohydrates that provide calories (which excludes fiber and some sugar alcohols)"). This disclosure must appear immediately adjacent to or as part of the claim or be linked to the claim by an asterisk; and

(iii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower carbohydrate content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of meal products as defined in §101.13(l) or main dish products as defined in §101.13(m), provided that:

(i) The product contains 6 g or less of carbohydrate (excluding dietary fiber and the non-caloric proportion of sugar alcohols, as described in paragraph (c) of this section) per 100 g; and

(ii) The food contains less than 0.5 g per serving of the total of dietary fiber and the non-caloric proportion of sugar alcohols (as described in paragraph (c) of this section), unless it is labeled to disclose that the claim is based on carbohydrates that provide calories, excluding dietary fiber and the non-caloric proportion of sugar alcohols (for example, "Low in carbohydrates that provide calories (which excludes fiber and some sugar alcohols)"). This disclosure must appear immediately adjacent to or as part of the claim or be linked to the claim by an asterisk; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower carbohydrate content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms "reduced carbohydrate," "reduced in carbohydrate," "carbohydrate reduced," "less carbohydrate," "lower carbohydrate," or "lower in carbohydrate" may be used on the label or in the labeling of foods, except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:

(i) The food contains at least 25 percent less carbohydrate (excluding dietary fiber and the non-caloric proportion of sugar alcohols, as described in paragraph (c) of this section) per reference amount customarily consumed than an appropriate reference food as described in §101.13(j)(1); and

(ii) The food contains less than 0.5 g per serving of the total of dietary fiber and the non-caloric proportion of sugar alcohols (as described in paragraph (c) of this section), unless it is labeled to disclose that the claim is based on carbohydrates that provide calories, excluding dietary fiber and the non-caloric proportion of sugar alcohols (for example, “Reduced in carbohydrates that provide calories (which excludes fiber and some sugar alcohols)”). This disclosure must appear immediately adjacent to or as part of the claim or be linked to the claim by an asterisk; and

(iii) As required in §101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the carbohydrate differs between the two foods are declared in immediate proximity to the most prominent such claim (e.g., “reduced carbohydrate – 50 percent less carbohydrates than our regular yogurt”); and

(B) Quantitative information comparing the level of carbohydrate in the product per labeled serving with that of the reference food that it replaces (e.g., “Carbohydrate content has been reduced from 12 g to 9 g per serving”) is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with §101.2.

(iv) Claims described in paragraph (b)(4) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for “low carbohydrate.”

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in the labeling of meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:

(i) The food contains at least 25 percent less carbohydrate per 100 g of food than an appropriate reference food as described in §101.13(j)(1); and

(ii) The food contains less than 0.5 g per serving of the total of dietary fiber and the non-caloric proportion of sugar alcohols (as described in paragraph (c) of this section), unless it is labeled to disclose that the claim is based on carbohydrates that provide calories, excluding dietary fiber and the non-caloric proportion of sugar alcohols (for example, "Reduced in carbohydrates that provide calories (which excludes fiber and some sugar alcohols)"). This disclosure must appear immediately adjacent to or as part of the claim or be linked to the claim by an asterisk; and

(iii) As required in §101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the carbohydrate differs between the two foods are declared in immediate proximity to the most prominent such claim (e.g., "reduced carbohydrate spinach soufflé, 33 percent less carbohydrate per 3 oz than our regular spinach soufflé"); and

(B) Quantitative information comparing the level of carbohydrate in the product per specified weight with that of the reference food that it replaces (e.g., "Carbohydrate content has been reduced from 12 g per 3 oz to 9 g per 3 oz") is declared adjacent to the most prominent claim, to the nutrition label, or, if the nutrition label is located on the information panel, it may appear elsewhere on the information panel in accordance with §101.2.

(iv) Claims described in paragraph (b)(5) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low carbohydrate."

(c) *Non-caloric proportion of sugar alcohols.* To exclude the non-caloric proportion of sugar alcohols from total carbohydrate for purposes of making the claims in paragraph (b) of this section, the following quantities should be subtracted from each gram of the listed sugar alcohols: 0.95 g for erythritol; 0.6 g for mannitol; 0.5 g for isomalt; 0.5 g for lactitol; 0.475 g for maltitol; 0.4 g for xylitol; 0.35 g for sorbitol; 0.25 g for hydrogenated starch hydrolysates; and 0 g for glycerin.

(d) *Carbohydrate content claims for foods that are good or excellent sources of carbohydrate.*

(1) The terms "high," "rich in," or "excellent source of" may be used to refer to carbohydrate on the label and in the labeling of foods, except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m),

provided that the food contains at least 45 g total carbohydrate per reference amount customarily consumed, contains no more than 25 percent of calories from sugars, and contains at least 2.5 g dietary fiber per reference amount customarily consumed.

(2) The terms defined in paragraph (d)(1) of this section may be used on the label and in the labeling of meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:

- (i) The product contains a food that meets the definition of “high” in paragraph (d)(1) of this section; and
- (ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., “the serving of broccoli in this product is high in carbohydrate”).

(3) The terms “good source,” “contains,” or “provides” may be used to refer to carbohydrate on the label and in the labeling of foods, except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that the food contains at least 22.5 g total carbohydrate per reference amount customarily consumed, contains no more than 25 percent of calories from sugars, and contains at least 2.5 g dietary fiber per reference amount customarily consumed.

(4) The terms defined in paragraph (d)(3) of this section may be used on the label and in the labeling of meal products as defined in §101.13(l) and main dish products as defined in 101.13(m), provided that:

- (i) The product contains a food that meets the definition of “good source” in paragraph (d)(3) of this section; and
- (ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., “the serving of sweet potatoes in this product is a good source of carbohydrate”).

(d) *Synonyms.* For purposes of making the claims in paragraphs (b) and (d) of this section, “carb” may be used as a synonym for “carbohydrate.”

The following amendments are made to existing sections of 21 CFR:

§ 101.54 Nutrient content claims for “good source,” “high,” “more,” and “high potency.”

(a) *General requirements.* Except as provided in paragraph (e) of this section and in §101.____ (“Nutrient content claims for carbohydrate content of foods”), a claim about the level of a nutrient in a food in relation to the Reference Daily Intake (RDI) established for that nutrient in §101.9(c)(8)(iv) or Daily Reference Value (DRV) established for that nutrient in §101.9(c)(9), (excluding total carbohydrates) may only be made on the label or in labeling of the food if:

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§ 105.66 Label statements relating to usefulness in reducing or maintaining body weight.

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(e) *Label terms suggesting usefulness as low calorie or reduced calorie foods.*

(1) Except as provided in paragraphs (e)(2), (e)(3) and (e)(4) of this section
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(4) Paragraph (e)(1) of this section shall not apply to any representation of a product as a food for special dietary use based on its carbohydrate content, provided that, if such product does not meet the criteria in §101.60(b)(1) or (b)(2) for “calorie free” or “low calorie” claims, or the criteria in §101.____(b)(1), (b)(2) or (b)(3) for “carbohydrate free” or “low carbohydrate” claims, then such product shall be labeled with the statement, “See nutrition information for calorie content.” This statement must appear immediately adjacent to the representation of the product as a food for special dietary use.